



19 Dec'd 2005 19 DEC 2005

PTO/SB/08A (07-05)

Approved for use through 07/31/2008. OMB 0651-0031

Approved for use through 01/06/2008. GPO 2007-093.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/527,618
Filing Date	03/10/2005
First Named Inventor	Au-Yeung, K. et al.
Art Unit	1637
Examiner Name	Suchira Pande
Attorney Docket Number	213-0084US

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner /Sushma Pandit/ Date

Signature /Suchira Pande/ Considered 10/24/2006
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language

Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

19 DEC 2005

PTO/SB/08B (07-05)

Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/527,618
				Filing Date	03/10/2005
				First Named Inventor	Au-Yeung, K. et al.
				Art Unit	1637
				Examiner Name	Suchira Pande
Sheet 2	of 2	Attorney Docket Number	213-0084US		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
SP	C1	Ciccolini et al. "Rheological Properties of Chromosomal and Plasmid DNA During Alkaline Lysis Reaction" Bioprocess Engineering 21 (1999) 231-237				
SP	C2	Levy et al. "Biochemical Engineering Approaches to the Challenges of Producing Pure Plasmid DNA" Trends in Biotechnology 18 (2000) 296-305				
SP	C3	Theodossiou et al. "Methods of Enhancing the Recovery of Plasmid Genes From Neutralised Cell Lysate" Bioprocess Engineering 20 (1999) 147-156				
SP	C4	Search Report for Application No. 03749647.8-2405 PCT. European Patent Office. 11/03/2005.				

Examiner Signature	/Suchira Pande/	Date Considered	10/24/2006
--------------------	-----------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

04 APR 2005

10 Rec'd PTO-1449
Page 1 of 5

Form PTO-1449 (modified)

Atty. Docket No. Serial No.
213-0084US 10/527,618

List of Patents and Publications for Applicant's

Inventor/Applicant

Kwok-Leung (Jackie) Au-Yeung, et al.

INFORMATION DISCLOSURE STATEMENT

Title: Apparatus and Method for Preparative
Scale Purification of Nucleic AcidsFiling Date: Group:
March 10, 2005 unknown

(Use several sheets if necessary)

U.S. Patent Documents
See Pages 1 - 3Foreign Patent Documents
See Page 3Other Art
See Page 3 - 5

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
SP	A1	3,286,992	11/22/1966	Armeniades, et al.			11/29/1965
	A2	3,928,642	12/23/1975	Hubert, et al.	426	521	01/22/1975
	A3	4,450,103	05/22/1984	Konrad, et al.	260	112	03/01/1982
	A4	4,462,940	07/31/1984	Hanisch, et al.	260	112	05/18/1983
	A5	4,621,061	11/04/1986	Pühler, et al.	435	320	12/13/1983
	A6	4,623,723	11/18/1986	Keller, et al.	536	27	03/09/1984
	A7	4,780,210	10/25/1988	Hsia	210	638	01/07/1987
	A8	4,830,969	05/16/1989	Holmes	435	259	08/31/1981
	A9	4,900,677	02/13/1990	Hewitt	435	259	09/26/1986
	A10	4,997,932	03/05/1991	Reardon, et al.	536	27	11/13/1989
	A11	4,985,552	01/15/1991	Fedeli, et al.	536	27	07/05/1989
	A12	5,008,189	04/16/1991	Oroskar, et al.	435	105	06/20/1989
	A13	5,034,314	07/23/1991	Geiger, et al.	435	6	12/22/1986
	A14	5,057,426	10/15/1991	Henco, et al.	435	270	11/23/1987
	A15	5,096,818	03/17/1992	DeBonnville	435	91	06/04/1990
	A16	5,208,160	05/04/1993	Kikyotani, et al.	435	270	04/22/1988
	A17	5,256,294	10/26/1993	Van Reis	210	637	09/17/1990
	A18	5,300,433	04/05/1994	Hrinda, et al.	435	238	09/25/1991
	A19	5,561,064	10/01/1996	Marquet, et al.	435	320.1	02/01/1994
▼	A20	5,576,196	11/19/1996	Horn, et al.	435	91.1	01/13/1995
SP	A21	5,707,812	01/13/1998	Horn	435	6	08/06/1996

EXAMINER: /Suchira Pande/ DATE CONSIDERED: 10/24/2006

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

H: 531561(B#SLOII.DOC)

BEST AVAILABLE COPY

Form PTO-1449 (modified)

Atty. Docket No. 213-0084US Serial No. 10/527,618

List of Patents and Publications for Applicant's

Inventor/Applicant

Kwok-Leung (Jackie) Au-Yeung, et al.

INFORMATION DISCLOSURE STATEMENT

Title: Apparatus and Method for Preparative Scale Purification of Nucleic Acids

(Use several sheets if necessary)

Filing Date: March 10, 2005 Group: unknown

U.S. Patent Documents

See Pages 1 - 3

Foreign Patent Documents

See Page 3

Other Art

See Page 3 - 5

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
SP	A22	5,792,651	08/11/1998	Colpan, et al.	435	270	10/11/1996
	A23	5,837,529	11/17/1998	Wan, et al.	435	259	04/15/1996
	A24	5,916,775	06/29/1999	Hayashizaki	435	91.1	06/18/1997
	A25	5,981,735	11/09/1999	Thatcher, et al.	536	25.4	02/12/1997
	A26	5,990,301	11/23/1999	Colpan, et al.	536	25.4	10/18/1996
	A27	6,011,148	01/04/2000	Bussey, et al.	536	25.4	08/01/1996
	A28	6,036,940	03/14/2000	Ju, et al.	424	9.52	11/12/1997
	A29	6,197,553	03/06/2001	Lee, et al.	435	91.1	11/07/1997
	A30	6,214,586	04/10/2001	McNeilly	435	91.1	12/08/1997
	A31	6,268,492	07/31/2001	Mittlestaedt, et al.	536	25.4	07/29/1999
	A32	6,277,648	08/21/2001	Colpan	436	177	06/02/1994
	A33	6,297,371	10/02/2001	Colpan, et al.	536	25.3	02/22/1999
	A34	6,313,285	11/06/2001	Butler, et al.	536	25.4	07/21/2000
	A35	6,492,164	12/10/2002	Crouzet, et al.	435	320.1	09/05/2000
	A36	6,503,738	01/07/2003	Thatcher, et al.	435	91.1	01/07/2003
	A37	6,617,443	09/09/2003	Hendriks, et al.	536	25.41	09/05/2002
	A38	6,730,781	05/04/2004	Wils, et al.	536	25.4	09/15/1998
	A39	6,750,333	06/15/2004	Kuhne	536	23.1	08/04/1998
	A40	6,825,012	11/30/012	Blanche, et al.	435	91.42	10/19/2001
	A41	2001/0034435	10/25/2001	Nochumson, et al.	536	23.1	01/29/2001
SP	A42	2001/0045359	11/29/2001	Cheng, et al.	204	547	07/13/2001

EXAMINER:

/Suchira Pande/

DATE CONSIDERED: 10/24/2006

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

Form PTO-1449 (modified)

Atty. Docket No.	Serial No.
213-0084US	10/527,618

List of Patents and Publications for Applicant's

Inventor/Applicant

Kwok-Leung (Jackie) Au-Yeung, et al.

Title: Apparatus and Method for Preparative Scale Purification of Nucleic Acids

Filing Date:	Group:
March 10, 2005	unknown

(Use several sheets if necessary)

U.S. Patent Documents

See Pages 1 - 3

Foreign Patent Documents

See Page 3

Other Art

See Page 3 - 5

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
SP	A43	2002/0198372	12/26/2002	Bridenbaugh, et al	536	25.4	07/23/1998

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
SP	B1	WO 98/11208	03/19/1998	WIPO	C12N	15/10	Yes
	B2	WO 98/30685	07/16/1998	WIPO	C12N	15/10	Yes
	B3	WO 99/63076	12/09/1999	WIPO	C12N	15/10	Yes
	B4	CA 2,474,436 (WO 03/070942)	08/28/2003	Canada	C12N	15/10	Yes
	B5	EP 0 240 191	10/07/1987	EPO	C12N	15/00	Yes
↓	B6	EP 0 376 080	07/04/1990	EPO	C12N	15/10	Yes
	B7	EP 0 431 905	06/12/1991	EPO	C12N	15/10	Yes
SP	B8	EP 0 517 515	12/09/1992	EPO	C12N	15/10	Yes

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SP	C1	Bioscience Contract Production Corp Flyer, "Plasmid DNA Production," (June 1999)
SP	C2	Birnboim, et al., "A Rapid Alkaline Extraction Procedure for Screening Recombinant Plasmid DNA," Nucleic Acids Res. 7, 1513-1523 (1979)
SP	C3	Carlson, et al., "Mechanical Description of Escherichia Coli For Plasmid Recovery," Biotechnology and Bioengineering 48, pp 303-315 (1995)

EXAMINER:	/Suchira Pande/	DATE CONSIDERED:	10/24/2006
-----------	-----------------	------------------	------------

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

H:531561(B#5L011.DOC)

BEST AVAILABLE COPY

Form PTO-1449 (modified)

Atty. Docket No. 213-0084US Serial No. 10/527,618

List of Patents and Publications for Applicant's

Inventor/Applicant

Kwok-Leung (Jackie) Au-Yeung, et al.

INFORMATION DISCLOSURE STATEMENT

Title: Apparatus and Method for Preparative Scale Purification of Nucleic Acids

Filing Date: March 10, 2005 Group: unknown

(Use several sheets if necessary)

Foreign Patent Documents

See Page 3

Other Art

See Page 3 - 5

U.S. Patent Documents

See Pages 1 - 3

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SP	C4	Chandra, et al., "Large-Scale Purification of Plasmid DNA by Fast Protein Liquid Chromatography Using a Hi-Load Q Sepharose Column," <i>Analytical Biochemistry</i> , 203: 169-172 (1992)
	C5	Coppella, et al., "Isolation of High-Molecular-Weight Nucleic Acids for copy Number Analysis Using High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , 402: 189-199 (1987)
	C6	Data Sheet TMAE (M), "Properties of the Tentacle Ion-Exchange Sorbents," http://www.chromatography.co.uk.products/bio/ds01.htm 08/26/2003
	C7	Davis, et al., Short Technical Reports, "Comparison of Plasmid DNA Preparation Methods for Direct Gene Transfer and Genetic Immunization," <i>Biotechniques</i> , 21:93-99 (July 1996)
	C8	Durland, et al., "Manufacturing and Quality Control of Plasmid-Based Expression Systems," <i>Advance Drug Delivery Reviews</i> 30: 33-48 (1998) Elsevier
	C9	Ferreira, et al., "Downstream Processing of Plasmid DNA for Gene Therapy and DNA Vaccine Applications," <i>Trends in Biotechnology</i> 18, pp 380-388 (September 2000)
	C10	Fractogel EMD Process Media Merck KGaA 8 pages
	C11	"Guide to Tentacle-Biochromatography Products," http://www.chromatography.co.uk/products/bio/summary.htm 08/26/2003
	C12	Horn, et al. "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Human Gene Therapy</i> , 6: 565-573 (May 1995)
	C13	Kahn, et al., "Purification of Plasmid DNA by Tangential Flow Filtration," <i>Biotechnology and Bioengineering</i> 69(1) 101-106 (2000)
	C14	Kenics, "Kenics Static Mixer Systems," 4 pages 03/01/1995
↓	C15	Lengsfeld, et al., "Shear-Induced Degradation of Plasmid DNA," <i>J Pharmaceutical Sciences</i> 91, 1581-1589 (July 2002)
SP	C16	Lesney, "It's Not Being Green?" <i>Today's Chemist at Work</i> , pp 33-34 (July 2002)

EXAMINER: /Suchira Pande/ DATE CONSIDERED: 10/24/2006

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

H-531561(B#5L011.DOC)

BEST AVAILABLE COPY

Form PTO-1449 (modified)

Atty. Docket No. 213-0084US Serial No. 10/527,618

List of Patents and Publications for Applicant's

Inventor/Applicant

Kwok-Leung (Jackie) Au-Yeung, et al.

INFORMATION DISCLOSURE STATEMENT

Title: Apparatus and Method for Preparative Scale Purification of Nucleic Acids

Filing Date: March 10, 2005 Group: unknown

(Use several sheets if necessary)

Foreign Patent Documents

See Page 3

Other Art

See Page 3-5

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SP	C17	Maniatis, et al., "Large-Scale Isolation of Plasmid DNA, Molecular Cloning: A Laboratory Manual, pp 85, 87, 90 and 91 (1982)
	C18	Marquet, et al., "Process Development for the Manufacture of Plasmid DNA Vectors for Use in Gene Therapy," BioPharm, 8(7) 26-37 (1995)
	C19	Marquet, et al., "Characterization of Plasmid DNA Vectors for use in Human Gene Therapy, Part 1," BioPharm, 42-50 (May 1997)
	C20	Merion, et al., "Purification of Supercoiled Plasmids from Crude Cell Lysates Using High Performance Anion Exchange Chromatography," BioTechniques 7(1) (1989) 60-67
	C21	Montbriand, et al., "Improved Method for the Removal of Endotoxin From DNA," Journal of Biotechnology 44: 43-46, (1996)
	C22	pAlliance Brochure – QIAGENews, "Contract Plasmid DNA Manufacturing Services for Clinical and Commercial Applications," Issue No. 2 (2000)
	C23	Prazeres, et al., "Large-Scale Production of Pharmaceutical-Grade Plasmid DNA for Gene Therapy: Problems and bottlenecks," Trends Biotechnol., 17, pp. 169-174 (1999)
	C24	Theodossiau, et al. "The Processing of a Plasmid-Based Gene from <i>E. Coli</i> . Primary Recovery by Filtration," Bioprocess Engineering, Vol. 16, (1997) 175-185.
	C25	Varley, et al., "Production of Plasmid DNA For Human Gene Therapy Using Modified Alkaline Cell Lysis and Expanded Bed Anion Exchange Chromatography" Bioseparation 8: 209-217 (1999)
↓	C26	"Clearance of Endotoxin From Solution by Absorptive filtration with Wartobind™ Membrane Asorbers," Sartorius Corporation, Developing Methods #7
SP	C27	Zasloff, et al., "a New Method for the Purification and Idetification of Covalently closed circular DNA Molecules," Nucleic Acids Research, 5: 1139-1153 (1978)

EXAMINER: /Suchira Pande/ DATE CONSIDERED: 10/24/2006

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

H: 531561(B#5L011.DOC)

BEST AVAILABLE COPY